

Draft Guidance – Not for Implementation

Compliance Guidance

The Mammography Quality Standards Act Final Regulations Document #4

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Mammography Standards Branch
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs**

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Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. XXXX, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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Compliance Guidance¹

The Mammography Quality Standards Act

Final Regulations Document #4

Background

The Mammography Quality Standards Act (MQSA) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations became effective **April 28, 1999**, and replaced the interim regulations (58 FR 67558 and 58 FR 67565).

The FDA is using a variety of efforts to educate the public about the final regulations. These efforts include making presentations at key professional meetings and providing informational materials to the public. The currently available documents include a quarterly newsletter *Mammography Matters* and an Internet home page (<http://www.fda.gov/cdrh/mammography>) containing all previously issued guidance, including the latest edition of "*Preparing for the MQSA Inspection*."

¹ This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the State or local authorities regarding their requirements.

Certification

Question: Our group practice interprets mammograms sent to us by other facilities under a contractual arrangement. This is the only service that we provide in the mammography area. Does my group practice need an MQSA certificate to interpret mammograms?

Answer: No. FDA's policy is that partial providers, (groups such as yours that provide only part of the services required for mammography), will be certified as part of a "system" for producing, processing, and interpreting mammograms.

The provider of some component of the system that performs mammography must take the lead in obtaining an MQSA certificate. FDA expects that, in most cases, the owner of an x-ray unit or units will apply for accreditation and receive a certificate. The application for accreditation must show that all components of the system used to produce, process, and interpret mammograms meet MQSA requirements. If one or more of the facilities for which you interpret mammograms is applying for accreditation and certification, your responsibility will be to provide them with information documenting that the physicians in your group meet MQSA quality standards requirements for interpreting physicians.

When the facilities performing mammography receive their MQSA certificate, you will be included for the purpose of interpreting mammograms for that facility. If you interpret mammograms for several facilities, your group will be included under several certificates. Conversely, if one of the facilities for which you interpret mammograms is not certified, it would be unlawful for that facility to continue to produce mammograms. Although, as mentioned above, the owner of the x-ray unit(s) will probably take the lead in obtaining the MQSA certificate in most cases, any partial provider in a "system" can apply for the MQSA certificate.

Your group practice could apply for accreditation and receive the certificate, as a part of a system. In that case, your practice would be responsible for assuring not only that your practice meets MQSA quality standards for interpreting physicians, but also that the facilities that produce and process the mammograms for your interpretation meet the quality standards that apply to them. Your practice would also be responsible for passing the review of clinical images from each facility that produces images for your interpretation, and for meeting the other requirements for accreditation. Finally, as an MQSA certificate holder, you would be responsible for paying an annual FDA MQSA inspection fee.

In summary, it is the MQSA certificate holder who ultimately will be held responsible for assuring that all MQSA requirements are met.

Personnel - General

21 CFR 900.12(a)(1-3)

Mammographic modality specific continuing education.

Question: What is the best way for personnel to document their mammography modality specific continuing education?

Answer: The best way to document mammography modality specific continuing education is to have the education provider list the mammography modality credit hour “breakdown” on the certificate. Currently, most certificates do not provide such a “breakdown”. FDA strongly encourages CME/CEU providers to provide this “breakdown” information on their certificates. Facilities are reminded that they are held responsible for maintaining documentation of their personnel’s mammography modality specific continuing education and should have begun collecting this documentation as of April 28, 1999. For those CME/CEU certificates that do not list the mammography modality credit hour “breakdown,” personnel may verify meeting this continuing education requirement by providing the CME/CEU certificate, a signed attestation form, and the course agenda or syllabus (see **limited attestation policy** in the Policy Guidance Help System available at <http://www.fda.gov/cdrh/mammography/robohelp/finalregs.htm>).

Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2004. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

21 CFR 900.12(a)(4)

Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.

Question: We use the same locum tenens interpreting physician (or “temporary” radiologic technologist) on a recurring basis throughout the year. Do we need to handle the personnel records for this person differently from our “permanent” interpreting physicians (radiologic technologists)? Which records will be reviewed at the time of our next inspection?

Answer: If the locum tenens interpreting physician (or “temporary” radiologic technologist) reads for (or performs mammograms for) the facility on a recurring basis throughout the year, the facility can treat this person as “permanent” for purposes of the annual inspection. In that event, the facility has to show that this person met all the requirements (including the continuing requirements, when appropriate) on the date of the inspection.

If the facility considered this person “temporary” and not working at the facility at the time of the inspection, the facility has to show that this person met all the requirements (including the continuing requirements, when appropriate) on each of the multiple occasions this person started reading (or performing mammograms) at the facility. For example, if the person worked for a week at a time starting the 15th day of each month, the facility is responsible for documenting that the person was qualified on each of those 12 occasions. This is not as daunting a task as it first appears. The facility needs to document that the person was fully qualified the first time he/she started working at the facility. In addition, in each of the calendar quarters the person worked, the facility needs to document (before letting the person provide mammography services) that the person met the

continuing requirements (when appropriate) and maintained a valid medical license (or valid State license or certification).

Radiologic Technologist

21 CFR 900.12(a)(2)(ii)

Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

- (A) Training in breast anatomy, physiology, positioning, compression, quality assurance/quality control techniques, imaging of patients with breast implants;*
- (B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and*
- (C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams;*

Question: I have my ARRT (M) certificate. Will this certificate be sufficient documentation to show that I received adequate training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques and imaging of patients with breast implants as specifically spelled out in 900.12(a)(2)(ii)(A)?

Answer: Yes. The ARRT (M) certificate will be accepted as documentation that the areas of training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques and imaging of patients with breast implants have been covered. Keep in mind that by being awarded the ARRT(M) certificate, you have earned 24 contact hours toward the required total of 40 contact hours of training.

Medical Physicist

21 CFR 900.12(a)(3)(i)

Initial Qualifications

- (A) Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and*
- (B)(1) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;*

Question: I have a masters (or higher) degree specifically in physics. Do I still need to document my number of semester hours in physics?

Answer: If the degree is stated to be specifically in physics (or any of its sub-specialties), it will routinely be accepted during inspections as adequate documentation of the required number of

semester hours in physics. Therefore, during routine inspections, you will not need to provide detailed transcripts to all the facilities where you provide physics services.

If the degree was stated to be in the more general term, physical science, or in one of the three non-physics categories of physical science (chemistry, radiation science, or engineering), you will have to provide additional documentation demonstrating compliance with the appropriate requirement for semester hours in physics.

21 CFR 900.12(a)(3)(ii)

Alternative initial qualifications.

(A) Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

(B) Prior to the April 28, 1999, have:

(1) A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,

Question: I have a bachelor's (or higher) degree specifically in physics. Do I still need to document my number of semester hours in physics?

Answer: If the degree is stated to be specifically in physics (or any of its sub-specialties), it will routinely be accepted during inspections as adequate documentation of the required number of semester hours in physics. Therefore, during routine inspections, you will not need to provide detailed transcripts to all the facilities where you provide physics services.

If the degree was stated to be in the more general term, physical science, or in one of the three non-physics categories of physical science (chemistry, radiation science, or engineering), you will have to provide additional documentation demonstrating compliance with the appropriate requirement for semester hours in physics.

Equipment

21 CFR 900.12(b)(8)(i)

Application of compression. Effective October 28, 2002, each system shall provide: (A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and (B) Fine adjustment compression controls operable from both sides of the patient.

Question: With machines such as the GE 500T and 600T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement?

Answer: Yes. After receiving input from the National Mammography Quality Assurance Advisory Committee, comments from the public, and performing its own evaluation, FDA has determined that, with proper use, fine compression can be achieved with GE 500T and 600T units by tapping the foot pedal. While FDA recognizes that fine compression can be achieved using these mammography units,

the specifics of the compression device require the technologist to pay additional attention during the application of compression. Where this causes clinical problems, facilities may want to consider modifying the compression device to allow for more consistent operator control. Facilities wishing to modify their units may contact their GE service representative for more information. Before a facility decides to modify the compression device, the facility should assure itself that the unit meets all the other new requirements (AEC performance, maximum compression force, focal spot condition and radiation output) that go into effect on October 28, 2002.

21 CFR 900.12(b)(10)

Automatic exposure control. (i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

Question: The regulations in 900.12(e)(5)(i) require that an x-ray unit pass an annual test for AEC performance over a range of 2 to 6 cm thick absorbers. If a unit is used clinically at combinations of kVp and filtration that include tissue thickness outside the 2 to 6 cm range, must it meet the AEC performance requirements at the thickness' where it operates and must it be tested at those technique factors under the annual quality control requirements?

Answer: No. The unit is not required to meet the AEC performance specification outside the 2 to 6 cm range and the physicist is not required to test the AEC performance requirements for thicknesses outside this range during the annual survey. However, we recommend that in addition to the required testing in the 2 to 6 cm range, the unit also be tested at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2-6 cm range, FDA recommends that a technique chart be developed showing appropriate techniques (kVp and density control settings) for the different breast thicknesses and compositions so that optical densities (OD) within ± 0.30 OD (± 0.15 OD after October 28, 2002) of the average under phototimed conditions can be produced.

NOTE: After October 28, 2002, the technique charts referred to in the preceding paragraph may be used only for thicknesses outside the 2-6 cm range. For use of technique charts within the 2-6 cm range, see Q/A regarding **use of manual techniques when the AEC fails**.

You should note that under the Equipment Evaluation outlined in 900.12(e)(10), an evaluation of the AEC under all clinically used configurations is required, not merely recommended, see guidance on **determining AEC performance during equipment evaluations**.

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Question: During an equipment evaluation, must AEC performance be tested for all equipment configurations used clinically by the facility or can it be limited to the contact configuration? What action limits apply?

Answer: During an equipment evaluation, the AEC must be operable in all equipment configurations (e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations) used clinically by the facility. Compliance with this requirement may be demonstrated by any of the following three methods:

1. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density (OD) over the 2-6 cm thick range within the action limit of ± 0.30 OD (± 0.15 OD after October 28, 2002) of the mean.

AND

Confirming AEC performance in all other clinically used configurations. This can be done by demonstrating that the AEC meets the density and reproducibility limits established by the manufacturer for those other configurations.

Note: Method #1 can be used only in those cases where the manufacturer has established AEC performance standards for the non-contact configurations provided.

2. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density over the 2-6 cm thick range within the action limit of ± 0.30 OD (± 0.15 OD after October 28, 2002) of the mean.

AND

Confirming AEC performance in all other clinically used configurations. This can be done by comparing the mean film optical density obtained from the data for the 2-6 cm thicknesses measured in the contact configuration with measurements obtained using the 4 cm thick phantom in the other configurations used clinically at the facility. When results across different configurations are compared, the facility may use the action limit of ± 0.30 OD even after October 28, 2002.

3. Confirming AEC performance by demonstrating that the AEC maintains the mean film optical density within ± 0.30 OD (± 0.15 OD after October 28, 2002) in all configurations used clinically by the facility. The action limit applies only within each specific configuration tested and does not apply to data collected across the different configurations.

Because of conflicting recommendations that currently exist in the professional community regarding measurement of AEC performance, facilities that currently are measuring AEC performance only in the contact configuration will not be cited for failure to measure AEC performance for all clinically used configurations until after October 28, 2002. (see guidance on **evaluating AEC performance during the annual physics survey**)

Medical Records

21 CFR 900.12(c)(1)(iv)

[The report shall contain] Overall final assessment of findings, classified in one of the following categories:

- (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);*
- (B) "Benign:" Also a negative assessment;*
- (C) "Probably Benign:" Finding(s) has a high probability of being benign;*
- (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;*
- (E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;*

21 CFR 900.12(c)(1)(v)

In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician;

Question: What assessment category should be used for post lumpectomy patients, whose mammograms are otherwise negative?

Answer: In the case described, the results could be categorized either as; "negative" or "benign." Where appropriate, qualifying statements such as "post surgical changes noted" may be added. The regulations require that each mammography report contain one of the six overall assessment categories. The decision as to which category to assign is left to the interpreting physician.

Question: Is the use of an assessment code (e.g. 0, 1, 2, 3, 4, 5 or N, B, P, S, M, A) without the wording of the assessment category (e.g. Negative, Benign, etc.) sufficient to satisfy the reporting requirement?

Answer: No. The wording of the assigned assessment category, chosen from one of the following; Negative, Benign, Probably Benign, Suspicious, Highly Suggestive of Malignancy, and Incomplete: Need additional imaging evaluation, must appear on the report.

Question: We provide assessment categories for each breast (or for each lesion) of the examination. Do we still have to provide one overall assessment category for the entire examination?

Answer: Yes. While individual assessments for each breast (or for each lesion), along with recommendations for their management, may be included in the report, one overall assessment category for the entire mammographic examination is required. It should be based on the assessment category of the more suspicious breast (or lesion).

21 CFR 900.12(c)(2)

Communication of mammography results to the patient. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility

shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(i) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.

(ii) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

Question: What type of lay summary should be sent to a patient who has a normal mammogram, but the facility is aware that the patient has an abnormal physical exam?

Answer: The facility has a great deal of flexibility in the format and substance of the lay summary. The lay summary must inform the patient of the results of the mammographic examination and follow-up actions, if needed. An acceptable lay summary could state that the mammogram was normal, but the patient should consult with the referring physician because of an abnormal physical exam.

21 CFR 909.12(c)(4)

Recordkeeping. Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

Question: With the introduction of Full Field Digital Mammography, what constitutes a mammogram, the digital data or the hard copy film?

Answer: There are two sections of the recordkeeping requirement that are impacted by the introduction of digital mammography. The first deals with retention of the mammography films. For purposes of film retention, the facility must maintain, in retrievable form, either the digital data or hard copy films for the specified periods of time. For purposes of transferring films, the facility must be able to provide the medical institution, physician, health provider, patient or patient's representative, with hard copy films of primary interpretation quality.

Quality Control (QC) Tests – General

Question: What are the minimum tests and/or reviews that the medical physicist must perform for a facility survey, survey of a mammography unit, equipment evaluation of a unit or processor that has been installed or disassembled and reassembled, and an equipment evaluation of a unit or processor that has undergone a major repair?

Answer:

Facility Survey	All tests as described in 900.12(e)(2), (e)(5), and if applicable (e)(6). Evaluate adequacy of the results of all tests conducted by the facility in accordance with 900.12(e)(1) through (e)(7)
Survey of a mammography unit	All tests as described in 900.12(e)(2), (e)(5), and if applicable (e)(6)
Equipment evaluation of a unit or processor that has been installed or disassembled and reassembled	All applicable tests and equipment requirements described in 900.12(b) and (e)
Equipment evaluation of a unit or processor that has undergone a major repair	Only those tests and equipment requirements described in 900.12(b) and (e) that are applicable to the repaired component of the unit or processor. The decision as to what constitutes applicable tests and equipment requirements for the repaired component should be made by the medical physicist.

For more information, check additional guidance about the specific item being installed, reassembled or repaired.

Question: While performing a physics survey, unit survey, or equipment evaluation, the medical physicist determines that the unit fails a required test(s) and needs to be adjusted or repaired. After the adjustment or repair has been completed, does the test(s) have to be repeated and must the medical physicist perform the test(s)?

Answer: After the adjustment or repair has been completed, the test(s) have to be repeated and must show that the unit is within the appropriate action limit before it can be used on patients. As to who must perform the test(s), if the adjustment or repair constitutes a “major repair (see **Medical Physicist Involvement in Equipment Repairs** table),” the medical physicist must repeat the test(s) as part of the required follow-up equipment evaluation. If the adjustment or repair does not constitute a “major repair,” the test(s) can be performed by any qualified person (e.g. radiologic technologist or service representative with appropriate training/experience). However, in this circumstance, FDA recommends, at a minimum, that the medical physicist be consulted during this process.

Question: Our facility has multiple mammographic units and uses several different screen-film combinations. What QC tests are we required to perform?

Answer: The required QC tests are summarized in the following table.

Table: Required QC Tests* for Facilities Using Multiple Units & Screen-Film Combinations

Test	Units Tested	S-F Combinations Tested With Each Unit
Focal Spot Condition a) System Resolution	All units**	For a), all S-F combinations clinically used with the unit in

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OR b) Focal Spot Dimensions (up to 10/28/2002)		question. For b), one S-F combination or direct exposure film.
Phantom Image	All units used to image the standard*** breast	All S-F combinations clinically used for the standard breast
Phantom Image	All units that are used <u>only</u> for non-standard breasts, and/or magnification work	One S-F combination, using clinical techniques that would be used for phantom images submitted to the accreditation body
Dose	All units used to image the standard breast	All S-F combinations clinically used for the standard breast with their corresponding techniques
Dose	All units that are used <u>only</u> for non-standard breasts, and or magnification work	One S-F combination, using clinical techniques that would be used for the standard breast
Darkroom Fog	Any unit (one only)	All film types clinically used
Uniformity of Screen Speed	Any unit (one only)	All clinically used screens (cassettes), one film type
Screen-Film Contact		
AEC Performance - Reproducibility	All units	One S-F combination (typically used with the unit)
AEC Performance – kVp & Thickness Tracking	All units used clinically in the 2-6 cm thickness range	One S-F combination (typically used with the unit)
Collimation System Artifacts	All units	One S-F combination (typically used with the unit)
kVp Accuracy & Reproducibility Decompression Radiation Output	All units	None

* This table does not cover other required QC tests that are independent of the x-ray unit or screen-film combination, e.g., the daily processor QC, the fixer retention, and repeat analysis.

** In this table, "All units" refers to those that are used clinically.

*** The standard breast referenced in this table is defined in the regulations as "a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue."

21 CFR 900.12(e)(1)

Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog

density, mid-density, and density difference, using the mammography film used clinically at the facility.

- (i) The base plus fog density shall be within + 0.03 of the established operating level.*
- (ii) The mid-density shall be within <plus-minus> 0.15 of the established operating level.*
- (iii) The density difference shall be within <plus-minus> 0.15 of the established operating level.*

21 CFR 900.12(e)(2)

Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

- (i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.*
- (ii) The optical density of the film at the center of the phantom image shall not change by more than <plus-minus> 0.20 from the established operating level.*
- (iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).*
- (iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than <plus-minus> 0.05 from the established operating level.*

Question: Our facility has permanently glued the acrylic contrast disk to the phantom at the center of the cover plate. The regulation states that the OD be measured at the center of the phantom which would require our repositioning the disk (which may leave permanent artifacts) or replacement of the phantom cover. Is there another way to leave the disk in place and still fulfill the requirement?

Answer: For the purpose of making the density measurements, FDA interprets measurements taken at the “center” of the phantom to be equivalent to measurements taken on the center line as described later in this paragraph. As an alternative to repositioning the disk or replacement of the phantom cover, you may choose to keep the disk in place (as is currently recommended by ACR). You may then measure the background density at a different location along the center line of the phantom in the direction parallel to the chest wall, as long as this location does not obscure any of the phantom objects. In addition, you must measure the background density at the same location each time the test is conducted.

You should be aware that if you remove the disk, permanent defects may be produced in the cover plate. Such defects may produce “permanent artifacts” in the phantom image. As long as these “permanent artifacts” do not interfere with the scoring of the phantom (do not simulate masses, fibers or specks, and do not obscure the test objects), facilities may continue to use the phantom. The facility should not subtract these “permanent artifacts” from the phantom score. However, if these “permanent artifacts” interfere with the scoring of the phantom (simulate masses, fibers or specks, and/or obscure one or more of the test objects), the defective portion of the phantom must be replaced. The facility should also be aware that any artifacts on phantom images submitted for accreditation purposes may reduce the phantom image final score, which in some cases may result in a phantom image failure.

21 CFR 900.12(e)(4)

Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(i) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

Question: We are a mobile facility with a van that does not have on-board processing. We have a film-changing room on the van where we load and unload cassettes with film during the day. When the van returns to our main office, we batch process the films. Do we have to perform a semiannual test for darkroom fog in this film-changing room?

Answer: Yes. Since you use a room to load and unload cassettes with film, you must test this room for darkroom fog as well as the darkroom for your processor. Both rooms have the potential to fog films and degrade image quality.

21 CFR 900.12(e)(4)

(iii) Compression device performance.

(A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

Question: During clinical exams, how long must our mammography unit maintain the final compression force set by the radiologic technologist?

Answer: The regulations do not specify a time frame in seconds or minutes. Instead, the minimum time frame is determined by the conditions at each facility. During clinical exams, the mammography unit must maintain the final compression force set by the radiologic technologist until the exposure is completed. If the radiologic technologist or interpreting physician notices that the compression force decreases significantly (adversely affects image quality) before the exposure is completed, the unit must be fixed, modified, or replaced.

Question: When I perform the semiannual compression QC test, our unit's initial power drive provides an initial compression force of 37 pounds, however, it cannot maintain that force. The force decreases to less than 25 pounds in approximately 1 second. How long does the initial power drive have to maintain a force of at least 25 pounds?

Answer: If the initial power drive is the sole means of providing compression for this mammographic unit, the unit must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations (**see previous question**), the unit must be repaired, modified or replaced.

If the unit also has fine adjustment control (required on all units as of October 28, 2002), the initial power drive must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to engage the fine adjustment control. The fine adjustment control must then maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations (**see previous question**), the unit must be repaired, modified or replaced.

QC Tests - Annual

21 CFR 900.12(e)(5)

Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

- (i) *Automatic exposure control performance.*
 - (A) *The AEC shall be capable of maintaining film optical density within <plus-minus> 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within <plus-minus> 0.30 of the average under phototimed conditions can be produced.*
 - (B) *After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within <plus-minus> 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.*
 - (C) *The optical density of the film in the center of the phantom image shall not be less than 1.20.*

Question: The regulations in 900.12(e)(5)(i) require that an x-ray unit pass an annual test for AEC performance over a range of 2 to 6 cm thick absorbers. If a unit is used clinically at combinations of kVp and filtration that include tissue thickness outside the 2 to 6 cm range, must it meet the AEC performance requirements at the thickness' where it operates and must it be tested at those technique factors under the annual quality control requirements?

Answer: No, the unit is not required to meet the AEC performance specification outside the 2 to 6 cm range and the physicist is not required to test the AEC performance requirements for thickness' outside this range during the annual survey. However, we strongly recommend that in addition to the required testing in the 2 to 6 cm range, the unit also be tested at all clinically used thickness' outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2-6 cm range, FDA recommends that a technique chart be developed showing appropriate techniques (kVp and density control settings) for the

different breast thicknesses and compositions so that optical densities within ± 0.30 (± 0.15 after October 28, 2002) of the average under phototimed conditions can be produced.

NOTE: After October 28, 2002, the technique charts referred to in the preceding paragraph may be used only for thicknesses outside the 2-6 cm range. For use of technique charts within the 2-6 cm range, see Q/A regarding **use of manual techniques when the AEC fails**.

You should note that under the Equipment Evaluation outlined in 900.12(e)(10), an evaluation of the AEC under all conditions of use is required, not merely recommended. This is because 900.12(e)(10) mandates conformance with all pertinent aspects of 900.12(b) and (e). Under 900.12(b)(10), the AEC is required to be “operable” under “configurations provided.” In this context, “operable,” as applied to the AEC means that it must meet the density and reproducibility requirements of (e)(5)(i) within the range of 2 to 6 cm. If designed to operate outside that range, the unit must meet the manufacturer’s specifications over such additional ranges.

Question: During the annual physics survey, must AEC performance be tested for all equipment configurations used clinically by the facility or can it be limited to the contact configuration? What action limits apply?

Answer: During the annual physics survey, AEC performance in the contact configuration must be tested. The medical physicist does not have to test the other clinically used equipment configurations during the annual physics survey, see guidance on **determining AEC performance during equipment evaluations**. In the contact configuration, the action limit requires maintenance of the film optical density (OD) over the 2-6 cm thickness range within ± 0.30 OD (± 0.15 OD after October 28, 2002) of the mean.

(iv) *Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Sec. 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.*

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

Question: Must the compression paddle be placed in the x-ray beam during half value layer (HVL) measurements?

Answer: If the HVL measurement is being used to calculate patient dose, the compression paddle must be placed in the x-ray beam during the measurement. If the HVL measurement is being used for purposes other than patient dose, the position of the paddle is not specifically stated in the regulations. However, FDA recommends inclusion of the compression paddle in the x-ray beam because most manufacturers have designed their equipment to be tested in this configuration.

(vii) X-ray field/light field/image receptor/compression paddle alignment.

(A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

(B) If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

Question: Do all possible combinations of beam-limiting devices, image receptor sizes, target materials, and focal spots have to be tested during the annual x-ray field/light field/image receptor alignment quality control test?

Answer: No. When performing the annual quality control test, the x-ray field/light field/image receptor alignment test must be performed only for those combinations of beam-limiting devices, image receptor sizes, target materials and focal spots used by the facility to produce full-field clinical images in the contact mode. For example, most facilities perform full-field clinical images using the large focal spot(s) in the contact mode. In this case, the alignment test has to be done only in the contact mode using the large focal spot(s). However, if, in addition to the large focal spot, the facility also routinely uses the small focal spot(s) to produce full-field clinical images in the contact mode, then the x-ray field/light field/image receptor alignment test must also be performed using the small focal spot(s). Facilities that only use the small focal spot to perform magnification or coned/spot images do not have to perform the alignment test in these configurations.

Medical Physicist's Annual Survey

21 CFR 900.12(e)(9)

Surveys.

- (i) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.*
- (ii) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.*

- (iii) *The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.*
- (iv) *The survey report shall be sent to the facility within 30 days of the date of the survey.*
- (v) *The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.*

21 CFR 900.12(e)(10)

Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

Question: What constitutes an equipment evaluation (what tests must the medical physicist perform) for a processor that has undergone major repairs or is a new processor to the facility?

Answer: At a minimum, the following tests must be done for a processor that has been replaced, undergone major repairs, or is a new processor to the facility: processor testing as described in 900.12(e)(1), phantom testing as described in 900.12(e)(2), and system artifact evaluation as described in 900.12(e)(5)(ix). If the major repairs or the use of the new processor necessitates a change in clinical technique factors (for the standard breast) that could significantly increase patient dose, a determination of dose as described in 900.12(e)(5)(vi) must be done.

Question: Must the equipment evaluation report be sent to the facility within 30 days?

Answer: The regulations do not specify when the equipment evaluation report must be sent to the facility. However, the facility cannot use the equipment until it has documentation (written preliminary or final equipment evaluation report) showing that the equipment passes all the appropriate tests.

Question: The bucky assembly (cassette holder) is being replaced on our x-ray unit. Is it necessary that the medical physicist test and pass this prior to its use on patients?

Answer: If the replacement includes the AEC detector, the medical physicist must evaluate the assembly prior to use on patients. If, however, the installation does not involve the replacement of the AEC detector(s) on the system, the exchange of Bucky assemblies would not be considered a major repair and would therefore not require the medical physicist to evaluate the assembly prior to use on patients. There are tests that should be performed when the bucky is replaced (table artifacts, grid

artifacts, and x-ray field/image receptor alignment). These particular tests require evaluation of images obtained with the new or modified equipment. In many cases, such images may be generated by facility personnel in consultation with the medical physicist but do not require the medical physicist to be physically present in the facility. The images may then be sent to the medical physicist for evaluation. If approved by the medical physicist, the facility may begin using the equipment. The medical physicist can then repeat the tests at the next annual survey.

Question: Under what circumstances must our medical physicist actually visit our facility in order to successfully carry out his/her responsibility to oversee our equipment-related quality assurance practices?

Answer: At a minimum, the medical physicist must be on-site to perform or to provide direct supervision for the performance of:

1. The annual survey;
2. Mammography equipment evaluations. A mammography equipment evaluation must be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor are changed or repaired.

Determining when a medical physicist must be on-site in connection with changes or repair of equipment can be confusing and requires further discussion. Changes or repairs of equipment can occur as corrective actions for problems that caused the equipment to fail a quality control test, as the result of an unexpected equipment failure, or as a measure intended to prevent possible future inadequate equipment performance. All changes or repairs must include some form of verification testing to demonstrate that the affected equipment meets the applicable standards.

As noted, in the case of changes or repairs to major equipment components, the medical physicist is required to come on-site to conduct a mammography equipment evaluation to confirm that applicable standards in 21 CFR 900.12(b) and (e) are met. FDA also recommends that the medical physicist have a role in some other changes or repairs through the provision of “medical physicist (MP) oversight.” By “MP oversight,” we mean that the medical physicist should be consulted as to whether an on-site visit is required or if other personnel can verify that the standards are met, with direction by telephone or printed material from the medical physicist if needed. Finally, FDA recognizes that there are changes or repairs for which verification (that the changed or repaired equipment meets standards) can be performed by other personnel without involving the medical physicist. However, the facility can consult their medical physicist in these situations if they wish.

The first column of the table, “Medical Physicist Involvement in Equipment Repairs,” lists the changes/repairs in which the regulations require a mammography equipment evaluation. It also includes a number of changes/repairs that do not require a mammography equipment evaluation. The second column indicates whether the item is considered by FDA to be a major change/repair. If so, it is stated in the third column that the “MP conducts evaluation in person.” For other changes/repairs, the third column indicates that FDA recommends either “MP oversight” or “MP involvement

optional.” In the cases where medical physicist involvement is not necessary, the verification may be accomplished by a qualified individual other than the medical physicist.

The fourth column of the table gives the time period within which it must be verified that the change or repaired equipment meets the applicable standards. It is important to remember that in all cases, even those where FDA is recommending “MP oversight” or verification by a non-medical physicist, that some form of verification testing must be included as part of the change or repair.

Table: Medical Physicist Involvement in Equipment Repairs

Item	Major Repair	Medical Physicist Involvement	Verification Period
Automatic Exposure Control			
AEC Replacement	Y	MP conducts evaluation in person	Before further use of item
Thickness compensation adjustment	Y	MP conducts evaluation in person	Before further use of item
AEC sensor replacement	Y	MP conducts evaluation in person	Before further use of item
AEC circuit board replacement	Y	MP conducts evaluation in person	Before further use of item
Density control - internal adjustment	N	MP oversight	Within 30 days*
Bucky (New to Facility) Replacement			
AEC also replaced	Y	MP conducts evaluation in person	Before further use of item
AEC not replaced	N	MP oversight	Before further use of item
Cassette replacement			
Same screen speed	N	MP involvement optional	Before further use of item
Different screen speed	N	MP oversight	Before further use of item
Collimator			
Replacement	Y	MP conducts evaluation in person	Before further use of item
Adjustment	N	MP oversight	Within 30 days*
Compression Device			
Pressure adjustment	N	MP involvement optional	Before further use of item
thickness scale accuracy adjustment but only if it affects AEC performance	N	MP oversight	Before further use of item
repair of auto decompression	N	MP involvement optional	Within 30 days*
Compression Paddle			
Paddle (new to facility) replacement	N	MP oversight	Before further use of item
Deflection adjustment	N	MP oversight	Before further use of item
Adjustment due to extension beyond allowable limit, or visibility on images	N	MP oversight	Before further use of item
Darkroom			
Repair of light leaks	N	MP involvement optional	Before further use of item
Safe light change	N	MP involvement optional	Before further use of item
Film type change	N	MP involvement optional	Before further use of item

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Filter Replacement	Y	MP conducts evaluation in person	Before further use of item
kVp internal adjustment	N	MP oversight	Within 30 days*
Processor			
Chemistry type change	N	MP involvement optional	Before further use of item
Chemistry type change leading to establishment of new operating levels	N	MP involvement optional	See guidance on establishing new operating levels
Fixer/Developer replacement	N	MP involvement optional	Before further use of item
Fixer/Developer replacement leading to establishment of new operating levels	N	MP involvement optional	See guidance on establishing new operating levels
Installation	Y	MP conducts evaluation in person	Before further use of item
Reassembly	Y	MP conducts evaluation in person	Before further use of item
Replenishment adjustment	N	MP involvement optional	Before further use of item
Replenishment adjustment leading to establishment of new operating levels	N	MP involvement optional	See guidance on establishing new operating levels
Roller replacement	N	MP involvement optional	Before further use of item
Radiation Output internal adjustment	Y	MP conducts evaluation in person	Before further use of item
X-ray Tube Replacement	Y	MP conducts evaluation in person	Before further use of item
X-ray Unit			
High voltage generator adjustment	Y	MP conducts evaluation in person	Before further use of item
High voltage generator replacement	Y	MP conducts evaluation in person	Before further use of item
Installation	Y	MP conducts evaluation in person	Before further use of item
Reassembly	Y	MP conducts evaluation in person	Before further use of item

* Within 30 days of the adjustment/repair or within 30 days of the date of the abnormal test leading to the adjustment/repair, whichever comes first

21 CFR 900.12(e)(13)

Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

- (i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and*
- (ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or*
- (iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.*

Question: We clean the mammography unit between each patient. Do we still have to document (through the use of logs or charts) cleaning after the equipment comes in contact with blood or other potentially infectious materials?

Answer: The regulations require that equipment be cleaned and disinfected after contact with blood or other potentially infectious materials. Many facilities perform routine cleaning between all patients. However, in most cases, this routine cleaning is not sufficient to disinfect the equipment, either because different materials are required or the materials used are not left in contact with the equipment for a sufficient amount of time to achieve disinfection. Because of this, and the importance FDA places on this aspect of quality assurance, the facility is required to maintain a record of those instances when disinfection procedures were performed.

Question: We use our mammography unit for interventional procedures as well as for routine mammography. Since interventional procedures are currently excluded from regulation, what should we be doing to document that proper infection control procedures have been performed?

Answer: While interventional mammographic procedures are currently excluded from regulation, the regulations regarding the use of infection control procedures in patients undergoing non-interventional (“screening or diagnostic”) mammography are clear. The facility must document that the equipment was cleaned and disinfected after contact with blood or other potentially infectious materials, prior to use on these non-interventional mammography patients, regardless of how or when the equipment was contaminated.

Question: We use our mammography unit solely for interventional procedures. Since interventional procedures are currently excluded from regulation, what are we required to do with respect to infection control procedures?

Answer: Because interventional mammographic procedures are currently excluded from regulation, there are no requirements imposed on a facility that does not do “screening or diagnostic” mammography. However, because of the high probability of contamination with blood or other infectious materials during interventional procedures, FDA strongly recommends that such facilities document that they clean and disinfect their equipment after each of their patients.

Mammography Medical Outcomes Audit

21 CFR 900.12 (f)(1)

General requirements.

Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician’s mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently became known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

Question: Are medical outcomes audit data collected during facility inspections used in a national database?

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Answer: No. While medical outcomes audit data are reviewed during the inspection to assure the facility is complying with the regulations, the data are not routinely collected by FDA. FDA does not maintain or supply information to such a national database.